IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Civil No.
	)	
v.	)	
	)	
CONGRESSIONAL SEAFOOD COMPANY, INC., a corporation, and STANLEY S. PEARLMAN, JONATHAN D. PEARLMAN AND STEPHEN G. BARDSLEY, individuals,	)	CONSENT DECREE OF PERMANENT INJUNCTION
	)	
Defendants.	)	

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for permanent injunctive relief against Congressional Seafood Corporation, Inc. ("Congressional"), a corporation, and Stanley S. Pearlman, Jonathan D. Pearlman, and Stephen G. Bardsley, individuals (hereinafter, collectively, "defendants"), and the defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against the defendants under the Federal Food, Drug, and

Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("the Act").

3. The defendants violate 21 U.S.C. § 331(a) of the Act by introducing, and causing the introduction into interstate commerce of, fish and fishery products, articles of food within the meaning of 21 U.S.C. § 321(f) (hereafter, "food"), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4). The defendants also violate 21 U.S.C. § 331(k) of the Act by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment in interstate commerce. The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

4. The defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) from preparing, packing, holding, and distributing, at or from Congressional's facility located at 7901 Oceano Avenue, Jessup, Maryland ("processing facility"), and at or from any other locations at which the defendants prepare, pack, hold, and distribute food, any fish or fishery products, unless and until:

A. The defendants have selected a person ("expert"), who is without any personal or financial ties (other than the consulting agreement) to the defendants or their families and who, by reason of background, experience, and education, is qualified to: (1) conduct hazard analyses and to develop adequate written hazard analysis critical control point ("HACCP") plans for the processing of fish and fishery products at Congressional as required by 21 C.F.R. § 123.6(a)-(c); (2) verify the adequacy of HACCP plans, as required by 21 C.F.R. § 123.8; (3) develop adequate Sanitation Standard Operating Procedures ("SSOPs") specific to Congressional, as required by 21 C.F.R. § 123.11; and (4) evaluate the defendants' monitoring of key sanitation conditions and practices, as set forth in 21 C.F.R. § 123.11(b);

B. The expert selected by defendants has: (1) verified that defendants' current HACCP plans will effectively control the hazards associated with each fish and fishery product, as required by 21 C.F.R. § 123.8; and (2) in the event that existing HACCP plans do not effectively control the hazards associated with each product, developed adequate, facility specific, written HACCP plans for each type of fish and fishery product prepared, packed, held, and distributed by the defendants that will effectively control the hazards associated with each product, as required by 21 C.F.R. § 123.6; and (3) evaluated the implementation of these plans, as required by 21 C.F.R.

§ 123.6(b); and (4) evaluated the verification procedures, as required by 21 C.F.R. § 123.8; and (5) developed adequate, facility-specific SSOPs for Congressional, as required by 21 C.F.R. § 123.11; and (6) evaluated the defendants' monitoring and recording of key sanitation conditions and practices, as set forth in 21 C.F.R. § 123.11(b) and (c);

C. The expert selected by defendants has provided the defendants with training, both oral and written, on appropriate methods to adequately maintain and monitor sanitation conditions and practices;

D. The defendants have provided the United States Food and Drug Administration ("FDA") with written verification procedures for every imported fish or fishery product, as required by 21 C.F.R. § 123.12;

E. The FDA has approved in writing the HACCP plans and the SSOPs developed by the expert, and the written verification procedures for every imported fish or fishery product required by 21 C.F.R. §§ 123.6, 123.11, and 123.12. FDA's review of the documents submitted pursuant to this subparagraph shall be completed within ten (10) business days after receiving such documents, or as soon thereafter as is reasonably practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled.

F. FDA, as it deems necessary, has inspected the processing

facility, including all records relating to the preparing, packing, holding, and distribution of fish and fishery products. Any inspection by FDA pursuant to this subparagraph will be initiated within five (5) business days after approving the documents specified in paragraph 4(E), or as soon thereafter as is reasonably practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled. The costs of FDA inspections conducted pursuant to this paragraph (including sampling, testing, travel, document preparation and review time, and subsistence expenses) shall be borne by the defendants at the rates specified in paragraph 16; and

G. FDA has notified the defendants, in writing, that the defendants appear to be in compliance with all of the requirements specified in paragraph 4(A)-(F) of this Decree, the Act, and all applicable regulations.

5. The defendants shall implement the HACCP plans, the SSOPs, and the verification procedures required by 21 C.F.R. §§ 123.6, 123.11, and 123.12 to the satisfaction of FDA.

6. Within fifteen (15) calendar days after the entry of this Decree, the defendants shall provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of the defendants' agents, representatives, attorneys, successors, and assigns. The defendants shall also post a copy of this Decree in the employee

common areas at the processing facility. The defendants agree to review with all of Congressional's employees, each requirement and the resulting obligations of this Decree within fifteen (15) calendar days after entry of this Decree.

7. Within twenty (20) calendar days after the entry of this Decree, the defendants shall provide the Director, FDA Baltimore District Office, at the address set forth in paragraph 20, and plaintiff's attorneys, an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of defendants' compliance with paragraph 6, and identifying the names and positions of all persons who were notified pursuant to paragraph 6.

8. The defendants agree to review with all new employees hired by Congressional, each requirement and the resulting obligations of this Decree within fifteen (15) calendar days after hiring each new employee and to certify in writing to FDA compliance with this requirement.

9. The defendants assert that Thomas P. Spencer no longer participates in any capacity with respect to the management or operations of Congressional and will not participate in any capacity with respect to the management or operations of Congressional so long as this Decree is in effect.

10. Within thirty (30) calendar days after the defendants receive the notice from FDA described in paragraph 4(G):

A. The defendants shall retain an independent person or persons (the "Auditor") to conduct audit inspections of the processing facility not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of two (2) years thereafter, for a total of three (3) years of auditing. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the consulting agreement) to the defendants or their families.

B. The audit shall evaluate whether the defendants are maintaining the processing facility in compliance with the requirements of the Act and its implementing regulations, including, but not limited to, whether the defendants have maintained: (a) acceptable process monitoring procedures, equipment verifications, record keeping procedures, and corrective actions, (b) sanitation monitoring procedures, record keeping procedures, and corrective actions, as set forth in the SSOPs, and (c) the records required by 21 C.F.R. § 123.12.

C. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") identifying in detail any deviations from the requirements of 21 U.S.C. § 342(a)(4) ("Audit Report Observation"). As part of every Audit Report except the first, the Auditor shall assess the adequacy of corrective actions taken by the defendants to correct

all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to the defendants and FDA's Baltimore District Director, at the address specified in paragraph 20, no later than fifteen (15) calendar days after the date each audit inspection is completed. The defendants shall maintain the complete Audit Reports and all of their underlying data in separate files at the processing facility and shall make the Audit Reports and underlying data available to FDA upon request.

D. If an Audit Report contains any Audit Report Observations, the defendants shall, within ten (10) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies defendants that a shorter time period is necessary. If, after receiving the Audit Report, defendants believe that correction of an Audit Report Observation will take longer than ten (10) calendar days, defendants shall, within seven (7) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. Any such Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. The defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days of the defendants's receipt of an Audit Report, or within the time period provided in a

Correction Schedule approved by FDA, the Auditor shall review the actions taken by the defendants to correct the Audit Report Observations. Within ten (10) calendar days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected.

11. After the defendants receive written notification from FDA as specified in paragraph 4(G), the defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns and any and all persons in active concert or participation with any of them, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into, or causing the introduction or delivery for introduction into, interstate commerce any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Causing any article of food to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce; and

C. Failing to implement and continuously maintain the requirements of this Decree.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the defendants' facility, or of any new

location(s) and, without prior notice and as and when FDA deems necessary, to take any other measures necessary to monitor and ensure continuous compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include the taking of photographs and samples and the examination and copying of all records that relate to the preparing, packing, holding, and distribution of fish and fishery products. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. Such inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. The defendants shall promptly provide any information or records to FDA regarding the preparing, packing, holding, and distribution of fish and fishery products upon request. The defendants shall maintain copies of their HACCP plans, and all records required by their HACCP plans and 21 C.F.R. Part 123, at the processing facility in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plans and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

14. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a

sample or samples, or other information, that the defendants have failed to comply with any provision of this Decree, have violated the Act or FDA regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or FDA regulations, FDA may, as and when it deems necessary, order the defendants in writing to take appropriate action, including, but not limited to, ordering the defendants immediately to take one or more of the following actions:

A. Cease preparing, packing, holding, and distributing food, including any fish and fishery products;

B. Recall all articles of their products that have been distributed or are under the custody and control of the defendants, their agents, distributors, customers, or consumers;

C. Institute or re-implement any of the requirements set forth in this Decree; or

D. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring the defendants into compliance with this Decree, the Act, or FDA regulations. All costs of such recall(s) and corrective actions shall be borne by the defendants. The costs of FDA inspections, sampling, testing, document preparation and review time, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by the defendants at the rates specified in paragraph 16. This provision shall be

separate and apart from, and in addition to, all other remedies available to FDA.

15. Any cessation of operations or other corrective actions as described in paragraph 14 shall be implemented immediately upon receipt of the FDA notice and shall continue until the defendants receive written notification from FDA that their operations appear to be in compliance with the Act, FDA regulations, and this Decree.

16. The defendants shall pay the costs of FDA's supervision, inspection, analysis, review, and examination conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $85.49 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $102.49 per hour and fraction thereof per person for laboratory and analytical work; $0.55 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate, or the equivalent, for the areas in which the inspections are performed, per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. If any defendant(s) fails to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, such defendant(s) shall pay to the United States of America: three thousand ($3,000) in liquidated damages for each day such violation continues and an additional sum of one thousand ($1,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree. In addition, should any defendant distribute any adulterated fish or fishery product, such defendant(s) shall, in addition to the foregoing, pay to the United States as liquidated damages a sum equal to twice the retail value of such fish or fishery product. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional civil or criminal penalties to be paid by defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

18. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, the defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and

witnesses, and administrative court costs relating to such contempt proceedings.

19. The defendants shall notify in writing the FDA Baltimore District Director at the address specified in paragraph 20 of this Decree at least twenty (20) calendar days before any change in ownership or character of their business such as dissolution, assignment, bankruptcy, or sale resulting in emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Congressional, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may effect compliance with this Decree. The defendants shall provide a copy of this Decree to any proposed successor or assignee at least thirty (30) calendar days prior to making any assignment or transferring any interest in the company as described in this paragraph. The defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than fifteen (15) calendar days prior to such assignment or change in ownership.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

21. The defendants shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree

shall be reviewed by the Court, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

SO ORDERED:

Dated this 7th day of January, ~~2009.~~ 2010

Benson E. Legg
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

FOR DEFENDANTS

STANLEY S. PEARLMAN
Individually and as President of Congressional Seafood Co., Inc.

JONATHAN D. PEARLMAN
Individually and as Vice President of Congressional Seafood Co., Inc.

STEPHEN G. BARDSLEY
Individually and as HACCP Coordinator of Congressional Seafood Co., Inc.

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Attorney for Congressional Fish & Seafood, Inc.

Alan L. Fishbein
Attorney for Stanley S. Pearlman

Alan L. Fishbein
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Alan L. Fishbein
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